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I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2003903404 for a patent by IPHASE TECHNOLOGIES PTY. LIMITED as filed on 02 July 2003.

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Fourteenth day of July 2004

JULIE BILLINGSLEY
TEAM LEADER EXAMINATION
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AUSTRALIA

Patents Act 1990

PROVISIONAL SPECIFICATION

APPLICANT: I-PHASE TECHNOLOGIES PTY. LIMITED

NUMBER:

FILING DATE:

Invention Title: AUTOMATED RADIOACTIVE DOSE DISPENSER

The invention is described in the following statement:-

AUTOMATED RADIOACTIVE DOSE DISPENSER

Area Of The Invention

This invention relates to apparatus used in nuclear medicine and in particular to a means whereby a radioactive dose required can be provided to a syringe in an automated fashion which obviates the need for a person to actually handle the radioactive material.

Background To The Invention

It is common for radioactive fluids called radiopharmaceuticals or radiotracers to have applications in medical fields and in particular in the field of nuclear medicine. Conventionally the radiotracer to be injected is drawn into a syringe, usually by hand, and from behind a lead shielded screen.

In recent years with the emergence of Positron Emission Tomography (PET), which uses radionuclides (radioisotopes) of significantly higher radiation energy than used previously, has raised concern about the hand and body radiation doses received by a technologist/radiopharmacist preparing the syringes.

Despite awareness of this problem manufacturers have not managed to design automated equipment that is practical and capable of drawing radioactive doses with

dilution into a disposable sterile syringe. Items of apparatus currently directed to this problem are operated by means of a peristaltic pump for transferring the solution and the use of a volumetrically determined radiation dose means that estimates of the radiation to volume ratio must be made which process is not necessarily particularly accurate.

Such equipment also tends to be large complicated apparatus that cannot be used as stand alone equipment in laminar flow cabinets or on conventional bench tops.

Summary of The Invention

It is an object of this invention to provide a simple and accurate means of automatically filling disposable syringes with a radioactive solution (radiopharmaceutical) to be injected or infused into a patient which means minimises exposure to people associated with the procedure other than the patient.

The invention is an apparatus for automatically loading a disposable syringe with a radiopharmaceutical said apparatus being stand alone and lead shielded and including a syringe/shielded syringe cartridge holder and syringe, said syringe having needle means directed into a receptacle that is connected to radiopharmaceutical and non radioactive stock solutions in valved relationship with the receptacle, the flow of each solution to which is controlled by a microprocessor in conjunction with a

radiation detection means which ascertains the radiation dose of the fluid entering the receptacle and then the syringe.

It is preferred that the flow of each solution is induced by actuation of the syringe plunger by means of a linear drive.

It is preferred that the radiation detection means be a Geiger-Muller tube or PIN photodiode located behind a portion of tubing leading to the receptacle or collection site. It is further preferred that a dedicated disposable T shaped tubing assembly be used to connect both stock solutions through pinch valves back through to the collection site thereby providing ease of installation and a sterile fluid pathway.

It is also preferred that the radioactive stock solution be, for example, ^{18}FDG and the non radioactive stock solution be 0.9% NaCl although the choice of stock solutions is not limiting in the invention and any appropriate stock solutions may be used.

It is preferred that the apparatus be provided with built in lead shielding to allow the apparatus to be used as stand-alone equipment and that micro processor control be provided with a Programmable Logic Controller (PLC). It is further preferred that the PLC controls the automation of the apparatus and performs relevant mathematical calculations for dispensing a requisite dose and that this be operated by means of a

touch screen as a user friendly interface with the equipment. While the above is preferred any computer type interface may be used.

In order that the invention may be more readily understood an embodiment of it will be described herein by way of non limiting example.

The invention in one embodiment is an apparatus for the automatic filling of disposable syringes with a radioactive solution (radiopharmaceutical) for injection or infusion into a patient. The automated nature of the apparatus minimises the exposure to an unnecessary radiation dose of any person working in the relevant area while providing an accurate and reliable radioactive dose of the radiopharmaceutical.

The equipment or apparatus is provided with an encompassing lead shield which permits it to be used as stand alone equipment inside a conventional laminar flow cabinet without the need for extra radiation shielding.

The apparatus includes a syringe holder which permits the needle of the syringe to be positioned into a collection site or receptacle which is preferably a conventional disposable Luer Slip Injection Site. This receptacle is connected by tube means through disposable T shaped tubing one side of which leads to a vessel of radioactive stock solution and the other to a vessel of non radioactive stock solution.

Pinch valves are located on either side of the T shaped member for switching between the respective radioactive and non radioactive stock solutions.

The solution is drawn into the disposable syringe by actuation of the syringe plunger by means of a linear drive and the dosage of the radioactive solution is then effected by the radiation detector determining when the required radiation dose has passed to the collection site and the required volume being made up by dilution from the non radioactive stock solution.

The radioactive dose of the final solution is determined by a radiation detector, such as a Geiger-Muller tube or PIN photodiode located behind a portion of tubing leading from the T shaped member to the syringe.

The control of the apparatus is effected using the PLC which both controls the automation of the apparatus and performs relevant mathematical calculations for dispensing a requested dose.

The operation of the apparatus also includes a remote touch screen which provides user friendly operation of the apparatus. The arrangement is such that the requested radioactive dose and the required volume are entered via the touch screen or an external computer.

The apparatus of the invention provides a sterile, non-pyrogenic fluid pathway which transports the radiopharmaceutical and saline solution into the syringe through an easily changed pre-assembled sterile disposable kit.

It is further envisaged that in another embodiment of the invention a built in sterile air flow will be incorporated which will permit the apparatus to be operated on a bench or the like in a conventional room while still maintaining full compliance with a 3.5 class (A class) dispensing environment. This is achieved by directing the sterile unidirectional air flow towards the collection site or "Luer Slip Injection Site" which is penetrated by the syringe needle.

The invention lies in an automated means of preparing a dose of a radiopharmaceutical into a disposable syringe under computer control by means of a radiation detector to determine the radioactive dosage and dilution by a non radioactive solution to achieve a desired volume. By this means such a dose can be prepared without unnecessary radiation exposure occurring to the person preparing the dose.

The precise components of the apparatus of the invention may be varied provided they achieve the method of the invention as described. It is further envisaged that other embodiments of the invention will exhibit any number of and any combination of the features of those previously described and whilst we have described herein

one specific embodiment of the invention it is to be understood that variations and modifications in this can be made without departing from the spirit and scope thereof.

DATED THIS 2nd DAY OF JULY 2003

IPHASE TECHNOLOGIES PTY. LIMITED
By its Patent Attorneys
A TATLOCK & ASSOCIATES

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